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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/757,774

01/09/2001

Howard M. Dintzis

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8467

27500

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02/11/2005

PILLSBURY WINTHROP LLP

ATTENTION: DOCKETING DEPARTMENT

11682 EL CAMINO REAL, SUITE 200

SAN DIEGO, CA 92130

EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/757,774	DINTZIS ET AL.	
	Examiner	Art Unit	
	David A Saunders, PhD	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-52, 54-57, 59-62 and 65-87 is/are pending in the application.
- 4a) Of the above claim(s) 70-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-47, 49, 52, 60, 65 and 69 is/are rejected.
- 7) ☒ Claim(s) 48, 50-51, 54-57, 59, 61-62, 66-68 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/01/04 has been entered.

Claims 44-52, 54-57, 59-62 and 65-87 are pending. Claims 44-52, 54-57, 59-62 and 65-69 are under examination.

For claims 56-57, the examiner cannot determine what has been "currently amended". Examiner finds no change since the amendment of 10/14/03. Correct status must be indicated in the next response.

The amendment of 11/01/04 has overcome the following bases of rejection stated in the office action of 01/02/04:

The 112, first paragraph rejection.

The 102 rejection over Barstad et al.

The 102 rejection over Katz.

The following basis of rejection is maintained:

Claims 44-47, 49, 52, 60, 65 and 69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,340,460. Although the conflicting claims are not identical, they are not patentably distinct from each other because following applicant's amendment of 11/01/04, the examiner finds that steps b) and c) of instant claim 44 correspond

Art Unit: 1644

essentially to steps a) and b) of issued claim 1. step b) of instant claim 69 corresponds less clearly to step a) of issued claim 1, by virtue of the fact that "non-immunogenic" has been deleted from claim 69, step b); however, the examiner considers that the instantly recited "soluble carrier" would encompass the issued claim recited "nonimmunogenic soluble carrier". Since there is common subject matter encompassed by the pending and issued claims a disclaimer is required.

The amendment has necessitated the following new grounds of rejection.

Claim 69 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 69, step b) it is unclear as to what "soluble carrier" is being coupled. Is it the "non immunogenic soluble carrier" of step a), from which the "high molecular weight soluble carrier molecules" have been removed? Alternatively, is it the "high molecular weight soluble carrier molecule. In step b) at line 1, deletion of "non-immunogenic" has led to confusion.

Claim 69 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 69 contains new matter.

Given the fact that claim 69 can be read as encompassing two different embodiments in step b) (see 112, 2nd supra), claim 69 now contains new matter because the second of the above noted possible embodiments was not disclosed.

Claim 69 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has failed to enable the practice of the method of claim 69, for both of the embodiments encompassed in step b).

As noted supra (112, 2nd), a second possible embodiment of step b) is the case in which the epitope copies are coupled to the "high molecular soluble carrier molecules" of step a). Such have been disclosed by applicant as being immunogenic. There is no teaching of any method of coupling the epitopes to an immunogenic, high molecular weight soluble carrier so as "to yield a non-immunogenic epitope-coupled construct" as required at the conclusion of step b). Since one of skill would not expect the immunogenic nature of high molecular weight soluble carrier molecules to somehow magically be abrogated by the coupling process, an undue amount of experimentation would be required for this embodiment.

Claim 69 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Step b) of claim 69 is not enabled to "yield a non-immunogenic epitope-coupled constant".

This is a second and separate basis for non-enablement; as step b) is recited it, per se, is required to "yield a non-immunogenic epitope coupled construct. The disclosure however has taught that the mere process of coupling does not result in a non-immunogenic construct. To the contrary, the disclosure has taught that the process of coupling leads to undesired, immunogenic contaminants —e.g. due to the cross coupling of carriers; not until the coupled reaction product has been subjected to "size-fractionation", as in step c), does the overall process "yield a non-immunogenic epitope coupled construct".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00a.m to 5:30p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 1644

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/tgd

February 2, 2005

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644